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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/780,151

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Jay C. Pershing

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12/17/2009

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EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

12/17/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/780,151

Applicant(s)

PERSHING ET AL.

Examiner

Anne R. Kubelik

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13 and 15-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13 and 15-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 September 2009 has been entered.
2. Claims 13 and 15-36 are pending.
3. The rejection of claims 13-24 under 35 U.S.C. 103(a) as being unpatentable over Kennedy et al (1995, J. Econ. Entolmol. 88:454-460) in view of in view of Turnblad et al (1998, US Patent 5,849,320) is withdrawn in light of Applicant's amendment to the claims.

Claim Objections

4. Claims 19 and 22 are objected to because of their recitation of "8-endotoxin " in line 5. This should be replaced with -- δ -endotoxin--:

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Support for claims to a seed blend comprising a refuge seed is first found in Application 09/972, 012, filed 5 October 2001. Support for claims to seeds blends where a seed is

insecticidal to a lepidopteran pest is first found in Application 10/394, 929, filed 19 March 2003.

The priority dates for claims to these inventions is assigned accordingly.

7. Claims 17 and 18, and all dependent claims, are not interpreted as limiting the seed to having a seed treatment, as parent claims 15 and 16 only list possible treatment without the dependent claims requiring that the seed has it.

8. Claims 13, 15-27 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al (August 2000, International Rice Research Notes 25:4-10).

The claims are drawn to seed blends comprising seed comprising two insecticidal transgenes and a refuge seed not comprising the two insecticidal transgenes, wherein the seed comprising two insecticidal transgenes is 80% to 99% of the blend.

Cohen et al teach seed blends comprising a first transgenic crop comprising an insecticidal transgene and a refuge seed that does not comprise an insecticidal transgene (pg 5, right column, paragraph 4). Cohen et al teach that farmers must plant 4-20% of their crops as the refuge plant (pg 8, left column, paragraph 2). Cohen et al teach plants comprising the *Bacillus thuringiensis* δ -endotoxins Cry3A, Cry1Ac or Cry1Ab (Table on pg 7); Cry1Ab confers resistance to the lepidopteran European corn borer. Cohen et al teach plants comprising two insecticidal transgenes (pg 8, right column, paragraph 2, to pg 9, left column, paragraph 1), and that plants comprising two insecticidal transgenes should be grown with refuges (pg 9, left column, paragraph 4). Cohen et al do not teach seed blends comprising seed comprising two insecticidal transgenes and a refuge seed not comprising the two insecticidal transgenes.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the seed blends taught by Cohen et al to have the first transgenic crop comprise two transgenes. One of ordinary skill in the art would have been motivated to do so

because of the suggestion of Cohen et al to do so (pg 8, right column, paragraph 2, to pg 9, left column, paragraph 1 and 4).

Having the refuge seeds and the seeds comprising the insecticidal proteins be of the same variety would be obvious to one of skill in the art given that would allow the most uniformity in other traits for which the crop is grown.

It would have been obvious to one of ordinary skill in the art for both of the seeds in the seed blend to comprise a transgene conferring herbicide resistance to an herbicide like glyphosate, given its importance in farming methods.

9. Claims 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al as applied to claims 13, 15-27 and 33-36 above, and further in view of English et al (2000, US Patent 6,023,013).

The claims are drawn to seed blends comprising seed comprising two insecticidal transgenes and a refuge seed not comprising the two insecticidal transgenes, wherein the seed comprising two insecticidal transgenes is 80% to 99% of the blend, and wherein one of the two insecticidal transgenes is a Cry3Bb.

The teachings of Cohen et al are discussed above. Cohen et al do not teach seed blends in which one of the two insecticidal transgenes is a Cry3Bb.

English et al teach modified Cry3Bb genes, which confer resistance to the coleopterans southern and western corn rootworm (Table 2, 26-27).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the seed blends taught by Cohen et al to have one of the two insecticidal transgenes be a Cry3Bb taught by English et al and the other be Cry1Ab, which confers resistance to the lepidopteran European corn borer. One of ordinary skill in the art would have

been motivated to do so because the Cry3Bb variants have improved insecticidal activity (English et al, column 7, lines 21-41, column 35, lines 32-58, column 36, lines 35-46) and because use of two insecticidal transgenes would result in resistance to a greater range of pests.

10. Claims 27-28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al in view of English et al as applied to claims 29-31 above, and further in view of Narva et al (2000, US Patent 6,083,499).

The claims are drawn to seed blends comprising seed comprising two insecticidal transgenes and a refuge seed not comprising the two insecticidal transgenes, wherein the seed comprising two insecticidal transgenes is 80% to 99% of the blend, and wherein the two insecticidal transgenes are Cry3Bb and PS149B1.

The teachings of Cohen et al in view of English et al are discussed above. Cohen et al in view of English et al do not teach seed blends in which the other of the two insecticidal transgenes is PS149B1.

Narva et al teach PS149B1 toxins (column 19, line 1, to column 21, line 52). The PS149B1 toxins confer resistance to western corn rootworm (Table 7).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the seed blends taught by Cohen et al in view of English et al to have one of the two insecticidal transgenes be PS149B1. One of ordinary skill in the art would have been motivated to do so because insects feeding on plants with two toxins are less likely to develop resistance; thus, refuges can be smaller (Cohen et al, pg 8, right column, paragraph 2).

11. Claims 13, 15-27, 29-30 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maqbool et al (1999, Mol. Breed 5:471-480) in view of Cohen et al (August 2000, International Rice Research Notes 25:4-10).

The claims are drawn to seed blends comprising seed comprising two insecticidal transgenes and a refuge seed not comprising the two insecticidal transgenes, wherein the seed comprising two insecticidal transgenes is 80% to 99% of the blend.

Maqbool et al teach rice plants comprising three insecticidal transgenes, *Bacillus thuringiensis* δ -endotoxins Cry1Ac and Cry2A, and snowdrop lectin GNA (paragraph spanning pg 475-476). Cry1Ac and snowdrop lectin GNA confer resistance to lepidopterans, and Cry2A to coleopterans. Maqbool et al do not teach seed blends comprising 1-20% refuge seed.

The teachings of Cohen et al are discussed above.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the seed of the plants taught by Maqbool et al to provide it in blends with a refuge plants that does not contain the insecticidal transgenes, as described in Cohen et al. One of ordinary skill in the art would have been motivated to do so because Cohen et al teach that farmers must plant 4-20% of their crops as the refuge plant (pg 8, left column, paragraph 2); seed blends allow as easy method of ensuring the desired ratio.

Having the refuge seeds and the seeds comprising the insecticidal proteins be of the same variety would be obvious to one of skill in the art given that would allow the most uniformity in other traits for which the crop is grown.

It would have been obvious to one of ordinary skill in the art for both of the seeds in the seed blend to comprise a transgene conferring herbicide resistance to an herbicide like glyphosate, given its importance in farming methods.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 13 and 15-36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-40 of U.S. Patent No. 6,551,962.

Although the conflicting claims are not identical, they are not patentably distinct from each other. Methods of deploying a refuge crop in a field of transgenic pest resistant crops, said method comprising providing a mixture of transgenic crop seeds with about 1-20%, 2-5%, 5-10%, 1-10% or 10-20% non-transgenic refuge crop seeds, wherein the transgenic crop seeds comprise two or more insecticidal proteins, including Cry3Bb and the proteins in the instant claim 19, as claimed in the issued patent, make obvious seed blends comprising a mixture of transgenic crop seeds with about 1-20%, 2-5%, 5-10%, 1-10% or 10-20% non-transgenic refuge crop seeds, wherein the transgenic crop seeds comprise two or more insecticidal proteins, including Cry 3Bb and the proteins in the instant claim 19, as claimed in the instant application.

Further, methods comprising further treating the seeds with a pesticidal agent, including those in the instant claims 17 and 21, as claimed in the issued patent, make obvious the seed blends further comprising a pesticidal agent, including those in the instant claims 17 and 21, as claimed in the instant application.

Lastly, treating the seed blend with an herbicide, as claimed in the issued patent (claims 27 and 33), make obvious seed blends in which both the seeds comprise a transgene conferring herbicide tolerance, as claimed in the instant application. It would be obvious to one of skill in the art for the herbicide resistance gene to confer resistance to an herbicide like glyphosate, given its importance in farming methods.

Having the two transgenic proteins be Cry3Bb and PS149B1 or Cry3Bb and Cry22 are obvious given that these are three of the proteins listed in claim 25 of the issued patent. Cry3Bb

and Cry22 both confer resistance to the coleopteran western corn rootworm. Cry22 also confers resistance to the lepidopteran *Plutella xylostella*.

Having the refuge seeds and the seeds comprising the insecticidal proteins be of the same variety would be obvious to one of skill in the art given that would allow the most uniformity in other traits for which the crop is grown.

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, Ph.D., whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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December 17, 2009

/Anne R. Kubelik/
Primary Examiner, Art Unit 1638